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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,703	02/19/2004	Jong Seob Lee	012679-105	2018

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EXAMINER	
BAUM, STUART F	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,703	LEE ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *4 and 11-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence search results (3)*.

DETAILED ACTION

1. Claims 1-15 are pending.

2. Applicant's election without traverse of Group I, claims 1-3 and 5-10 in the reply filed on 3/13/2006 is acknowledged.

Claims 4, and 11-15 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 1-3 and 5-10, including SEQ ID NO:3 and SEQ ID NO:2 are examined in the present office action.

Specification/ Drawings

4. Figures 1A and 1B are objected to because they are too dark to discern any data. Correction is requested.

Objection is made to the specification for not incorporating SEQ ID NO's when referring to nucleic acid or amino acid sequences. 37 CFR 1.821(d) requires the use of the assigned sequence identifier (e.g. SEQ I.D. NO: X) in all instances where the description or claims of a patent application discuss sequences. In the instant application, Figure 3 discloses amino acid sequences that are not identified by sequence identifier. Correction is required.

Claim Objection

5. Claim 10 is objected to for reciting "plants is" instead of --plant is a--. Correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite for reciting "wherein the polynucleotide has the sequence of SEQ ID NO:3". The Office contends that SEQ ID NO:3 does not encode SEQ ID NO:2. According to the sequence search results, nucleotides 892-894 do not encode Alanine 188 of SEQ ID NO:2 (see enclosed sequence search result).

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3, and 5-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated polynucleotide encoding a polypeptide comprising an amino acid sequence having at least 70% sequence homology to SEQ ID NO:2, or wherein the

polynucleotide has the sequence of SEQ ID NO:3; a recombinant vector, cell, plant and method comprising said polynucleotide.

Applicants isolated their invention using an activation tagging approach (pages 18-19, Example 1). Applicants selected plants with a delayed flowering time and using plasmid rescue, isolated the putative gene which was responsible for the mutant phenotype. The isolated gene comprises 2606 base pairs with an open reading frame of 1140 base pairs, encoding a polypeptide of 379 amino acids (pages 20-22, Example 3). Applicants named the gene LONG VEGETATIVE PHASE 1 (LOV1), whose genomic and cDNA sequence are shown in SEQ ID NO:3 and 1, respectively, and the encoded protein is shown in SEQ ID NO:2 (page 22, lines 10-14). Applicants disclose the mutant phenotype of lov1-1D plants is a delay in flower initiation (pages 1920, Example 2).

As discussed in the 112 2nd rejection above, Applicants' SEQ ID NO:3 does not encode a polypeptide exhibiting 100% sequence identity with SEQ ID NO:2.

The Applicants do not identify essential regions of the LOV1 protein encoded by SEQ ID NO:1, nor do Applicants describe any polynucleotide sequences that encode a polypeptide having at least 70% sequence homology to SEQ ID NO:2 that encodes a functional LOV1 protein.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A

definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a LOV1 protein falling within the scope of the claimed genus of polynucleotides which encode a polypeptide having at least 70% sequence homology to SEQ ID NO:2. Applicants only describe a single cDNA sequence of SEQ ID NO:1 and a genomic sequence of SEQ ID NO:3, but the genomic sequence does not encode a polypeptide exhibiting 100% sequence identity with SEQ ID NO:2 (See 112 2nd rejection above). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the LOV1 protein, it remains unclear what features identify an Arabidopsis LOV1 protein of SEQ ID NO:2. Since the genus of LOV1 protein encoded by SEQ ID NO:1 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Enablement

8. Claims 1-3, and 5-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated polynucleotide encoding a polypeptide comprising an amino acid sequence having at least 70% sequence homology to SEQ ID NO:2, or comprising the amino acid sequence of SEQ ID NO:2, or wherein the polynucleotide has the sequence of SEQ ID NO:3; a recombinant vector, cell, plant comprising said polynucleotide and method for delaying the flowering time of plants comprising introducing said polynucleotide into plants, wherein the polynucleotide is operably linked to an expression control sequence.

Applicants isolated their invention using an activation tagging approach (pages 18-19, Example 1). Applicants selected plants with a delayed flowering time and using plasmid rescue, isolated the putative gene which was responsible for the mutant phenotype. The isolated gene

comprises 2606 base pairs with an open reading frame of 1140 base pairs, encoding a polypeptide of 379 amino acids (pages 20-22, Example 3). Applicants named the gene LONG VEGETATIVE PHASE 1 (LOV1), whose genomic and cDNA sequence are shown in SEQ ID NO:3 and 1, respectively, and the encoded protein is shown in SEQ ID NO:2 (page 22, lines 10-14). Applicants disclose the mutant phenotype of lov1-1D plants is a delay in flower initiation (pages 1920, Example 2). Applicants disclose the LOV1 gene has homology with *NAM*, *CUC1* and *CUC2* of *Petunia hybrida*, which are members of the NAC domain gene family (page 22, lines 5-8).

Applicants have not reduced to practice their invention. Applicants have only isolated a gene sequence which they purport is the gene responsible for the mutant phenotype. Applicants have not transformed any plant with SEQ ID NO:1 or 3 operably linked to a constitutive promoter and reproduced the mutant lov1-1D mutant phenotype. It is unclear if in fact the LOV1 gene is responsible for the mutant phenotype. Given the lack of certainty that the LOV1 gene is responsible for the mutant phenotype, undue additional experimentation would be required by one of skill in the art to make and/or use the claimed invention.

As discussed in the 112 2nd rejection above, Applicants' SEQ ID NO:3 does not encode a polypeptide exhibiting 100% sequence identity with SEQ ID NO:2. Because SEQ ID NO:3 does not encode SEQ ID NO:2, it is unclear if a plant over-expressing SEQ ID NO:3 would produce a phenotype of delayed flower initiation as proposed by applicant. Therefore, one skilled in the art would not be appraised of how to use a plant transformed with SEQ ID NO:3. Therefore Applicants' invention is not enabled.

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that encode a polypeptide having at least 70% sequence homology to SEQ ID NO:2 will encode a protein with the same activity as a protein encoded by SEQ ID NO:1. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

Applicants have not provided examples or guidance for selecting a sequence out of the multitude of sequences that are encompassed by Applicant's broad claim language, that gives the expected results when transformed into a plant. Transforming plants with heterologous genes that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1 is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant's broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a "range of phenotypes which include abnormalities in leaf and petal shape as well as stem height and number" (page 365, right column, 1st paragraph).

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:3 as probes or by designing primers to undisclosed regions of SEQ ID NO:2 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed, produce plants with a delayed flowering time.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al (2002, NCBI Accession Number BT000874).

The claims are drawn to an isolated polynucleotide encoding a protein comprising the amino acid sequence of SEQ ID NO:2, or wherein the polynucleotide has the activity of repressing flowering-promoting gene AGL20, a recombinant vector comprising said polynucleotide, or a cell comprising said polynucleotide.

Yamada et al disclose a nucleic acid sequence encoding a polypeptide exhibiting 100% sequence identity with SEQ ID NO:2 (see enclosed sequence search result). It would be inherent that said polynucleotide has the activity of repressing flowering-promoting gene AGL20. For purposes of molecular biology, said polynucleotide would be in a vector and transformed into a host cell, and as such, Yamada et al anticipate the claimed invention.

10. Claims 1-3, 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Rounsley et al (2002, NCBI Accession Number AC005312).

The claims are drawn to an isolated polynucleotide encoding a protein comprising an amino acid sequence having at least 70% sequence homology to SEQ ID NO:2, or wherein the polynucleotide has the sequence of SEQ ID NO:3, or wherein the polynucleotide has the activity of repressing flowering-promoting gene AGL20, a recombinant vector comprising said polynucleotide, or a cell comprising said polynucleotide.

Rounsley et al disclose a nucleic acid sequence encoding a protein exhibiting at least 70% sequence identity to SEQ ID NO:2, and wherein the polynucleotide exhibits 100% sequence identity with SEQ ID NO:3 (see enclosed sequence search result). It would be inherent that said polynucleotide has the activity of repressing flowering-promoting gene AGL20. For purposes of molecular biology, said polynucleotide would be in a vector and transformed into a host cell, and as such, Rounsley et al anticipate the claimed invention.

The Office notes that if SEQ ID NO:3 does in fact encode SEQ ID NO:2, then Rounsley et al anticipate a polynucleotide encoding SEQ ID NO:2.

11. Claims 1, 3, 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Colasanti et al (January 2001, U.S. Patent Number 6,177,614 B1).

The claims are drawn to an isolated polynucleotide encoding a protein comprising an amino acid sequence having at least 70% sequence homology to an amino acid sequence of SEQ ID NO:2, or wherein the polynucleotide has the activity of repressing flowering-promoting gene AGL20, a recombinant vector comprising said polynucleotide, or a cell comprising said polynucleotide, or a method for delaying the flowering time of plants comprising introducing said polynucleotide into plants, wherein the polynucleotide is operably linked to an expression control sequence.

The Office interprets "*an* amino acid sequence of SEQ ID NO:2" to read on a large number of sequences because the Office interprets said recitation to encompass nucleic acid molecules encoding any portion of SEQ ID NO:2 because of the article "*an*".

Colasanti et al disclose an isolated DNA comprising SEQ ID NO:1 which encodes a polypeptide comprising SEQ ID NO:2 (column 37, claims 1-7). Given the Office's interpretation of the claims as discussed above, the isolated DNA and polypeptide of Colasanti et al are encompassed in Applicants' broad claims. Colasanti et al discloses a recombinant vector comprising said sequence (see Figure 9A). For purposes of molecular biology, the recombinant vector would be transformed into E. coli. Colasanti et al discloses a method of producing transgenic plants having a delayed or inhibited time of flower induction comprising introducing said DNA into plants (column 38, claims 16 and 18) and as such, Colasanti et al anticipate Applicants' broadly claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claim 6 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claim recites "A cell comprising" which reads on a human being. Amending the claim to recite "An isolated cell" will obviate the rejection.

13. Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 8 is drawn to a seed of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed seeds, it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy , Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the seeds comprise the construct that was introduced into the parent would overcome the rejection.

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
April 28, 2006

STUART F. BAUM, PH.D.
PATENT EXAMINER